Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

HIV prophylaxis for victims of sexual assault.

Bibliographic Source(s)

New York State Department of Health. HIV prophylaxis for victims of sexual assault. New York (NY): New York State Department of Health; 2013 Jul. 12 p. [12 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. HIV prophylaxis following non-occupational exposure including sexual assault. New York (NY): New York State Department of Health; 2010 May. 56 p. [36 references]

Recommendations

Major Recommendations

The quality of evidence (I-III) and strength of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Important Note:

The preferred post-exposure prophylaxis (PEP) regimen for sexual assault is the same as that for other types of non-occupational exposures and occupational exposures:

Tenofovir 300 mg PO qd + Emtricitabine 200 mg PO qd

Plus

Raltegravir 400 mg PO bid

See HIV Prophylaxis Following Non-Occupational Exposure for regimen considerations when the source is known to be human immunodeficiency virus (HIV)-infected, dose adjustments for patients with renal insufficiency, drug-drug interactions, and recommended alternative regimens.

Introduction

Victims of sexual assault should be treated in an emergency department or equivalent healthcare setting where all appropriate medical resources are available as needed. (AIII)

Assessment to Determine Whether HIV PEP is Indicated Following Sexual Assault

When deciding whether to recommend the initiation of PEP following sexual assault, the clinician should assess and carefully weigh the following factors: (AIII)

- Whether or not a significant exposure has occurred during the assault
- Knowledge of the HIV status of the alleged assailant
- Whether the victim is ready and willing to complete the PEP regimen

The clinician's decision to recommend PEP should not be influenced by the geographic location of the assault. (AII)

Degree of Risk Based on Type of Exposure

Clinicians should recommend HIV PEP to victims when significant exposure may have occurred, as defined by direct contact of the vagina, penis, anus, or mouth with the semen, vaginal fluids, or blood of the alleged assailant, with or without physical injury, tissue damage, or presence of blood at the site of the assault. (AII)

PEP should also be offered in cases when broken skin or mucous membranes of the victim have been in contact with blood, semen, or vaginal fluids from the alleged assailant. Similarly, PEP should be offered in cases of bites that result in visible blood. (AII)

Considering the HIV Status of the Alleged Assailant

Unless the identity and HIV status of the alleged assailant has been clearly established to assist with the decision-making, PEP should be promptly initiated and should not be delayed while awaiting test results from the alleged assailant. (AII)

Even when the alleged assailant is known to be HIV-infected, the decision to recommend PEP should be based on the nature of the exposure and the victim's ability to complete the regimen. (AIII)

If PEP has been initiated and both the HIV rapid test and third- or fourth-generation enzyme-linked immunosorbent assay (EIA) or HIV ribonucleic acid (RNA) assay from the alleged assailant are found to be negative, then PEP should be discontinued. Decisions to discontinue PEP should be made in consultation with a clinician experienced in HIV PEP. (BIII)

Recommending PEP for Sexual Assault Victims

PEP should be initiated as soon as possible after exposure, ideally within 2 hours. (AII) Decisions regarding initiation of PEP beyond 36 hours post exposure should be made on a case-by-case basis with the realization that diminished efficacy is a consequence of delay in the timing of initiation (see HIV Prophylaxis Following Non-Occupational Exposure, Section IV: Timing of Initiation of PEP for all Non-Occupational Exposures). (AIII)

The recommendation for PEP should be communicated simply and clearly to the patient, considering his/her emotional state and ability to comprehend the nature of antiretroviral treatment. (AIII)

If a sexual assault victim is too distraught to engage in a discussion about PEP or make a decision about whether to initiate prophylaxis at the initial assessment, the clinician should offer a starter pack of medication and make arrangements for a follow-up appointment within 24 hours to further discuss the indications for PEP. (AIII)

If a sexual assault victim decides to initiate treatment, a follow-up visit should be scheduled within 24 hours to review the decision, evaluate initial drug tolerability, reinforce the need for adherence to the regimen, and arrange for follow-up care. (AIII) In New York State, hospitals providing treatment to victims of sexual assault must provide or arrange for an appointment for medical follow-up related to PEP and other care as appropriate. See the Voluntary HIV Provider Directory.

Discussions regarding initiation of PEP should include the following: (AIII)

- Potential benefit, unproven efficacy, and potential toxicity of PEP
- Duration of PEP regimen
- Importance of adherence to the treatment regimen to prevent PEP failure or the development of drug resistance should infection occur

- Need to reduce risk and prevent exposure to others
- Clinical and laboratory monitoring and follow-up schedule
- Signs and symptoms of acute HIV infection

HIV Testing of the Victim

Clinicians should perform baseline rapid HIV testing of the victim. PEP should be initiated without waiting for the results of the HIV test. (AIII)

Refusal to undergo baseline testing should not preclude initiation of PEP. (AIII)

> Key Point:
>
> A negative baseline HIV test only demonstrates that the victim was not previously infected with HIV before the exposure occurred; the baseline HIV test cannot determine whether the victim was infected as a result of the assault for which he/she is presenting.

Management of Sexually Transmitted Infections (STIs) Other Than HIV

For sexual assault victims, clinicians should offer prophylactic medication to prevent gonococcal and chlamydial infections. Routine baseline testing for STIs is not recommended in cases of sexual assault. (AIII)

Emergency Contraception

Clinicians should obtain baseline pregnancy testing for female sexual assault victims. (AII) Emergency contraception should be discussed and offered to women who have the potential of becoming pregnant as a result of the assault. (AII)

The Role of The Rape Crisis Advocate and Sexual Assault Examiner

The plan for follow-up care should be discussed with the rape crisis advocate or an outreach worker who will be working with the victim following the victim's departure from the emergency department or equivalent healthcare setting. (AIII)

Definitions:

Quality of Evidence for Recommendations

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Human immunodeficiency virus (HIV) infection

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Clinical Specialty

Allergy and Immunology

Critical Care

Emergency Medicine

Family Practice

Infectious Diseases

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

To address the unique considerations involved in evaluation, counseling, and support for human immunodeficiency virus (HIV) exposures resulting from sexual assault

Target Population

Individuals with human immunodeficiency virus (HIV) exposure from sexual assault

Interventions and Practices Considered

1. Treatment in an emergency department
2. Assessment of risk based on type of exposure
3. Consideration of assailant's human immunodeficiency virus (HIV) status, including testing when possible
4. HIV post-exposure prophylaxis (PEP)

5. Follow-up after treatment initiation
6. HIV testing of the victim
7. Prophylaxis against other infections, including gonorrhea and chlamydia
8. Pregnancy testing and emergency contraception
9. Involvement of a rape crisis advocate or outreach worker

Major Outcomes Considered

- Appropriate prophylaxis care for victims of sexual assault
- Degree of risk based on the type of exposure

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

MEDLINE was searched from January 2004 to December 2012 using appropriate key words. The inclusion used in the search were: Persons who were victims of sexual assault, non-HIV-infected victims of violence. The search terms used were: emergency contraception, sexual assault, rape against women AND HIV, intimate partner violence. (These criteria were used in addition to the searches done for *HIV Post Exposure Prophylaxis*).

Because there are no randomized controlled studies of this subject, the committee conducted its own review of evidence, including animal studies, mathematical and experimental models, and case reports. The Centers for Disease Control and Prevention reports from 1982 until 2012 were reviewed, as were models of transmission risk. The committee also reviewed medication efficacy and tolerability reports. The New York State Office of Victim Services was consulted and the http://aidsinfo.nih.gov/guidelines were reviewed.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Methods Used to Analyze the Evidence

Review

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physician's Prevention Advisory Committee
- Pharmacy Advisory Committee

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of human immunodeficiency virus (HIV) prophylaxis for victims of sexual assault

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

Implementation of the Guideline

Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers, and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC), and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio

conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

Implementation Tools

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2005 Dec (revised 2013 Jul)

Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

Source(s) of Funding

New York State Department of Health

Guideline Committee

Medical Care Criteria Committee

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Financial Disclosures/Conflicts of Interest

Not stated

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This guideline updates a previous version: New York State Department of Health. HIV prophylaxis following non-occupational exposure including sexual assault. New York (NY): New York State Department of Health; 2010 May. 56 p. [36 references]

Guideline Availability

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site .

Availability of Companion Documents

None available

Patient Resources

The following is available:

- I might have been exposed to HIV… What should I do? Electronic copies: Available in English and Spanish from the New York State Department of Health AIDS Institute Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on September 6, 2007. This summary was updated by ECRI Institute on June 26, 2008 and November 11, 2010. This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisory on Statins and HIV or Hepatitis C drugs. This NGC summary was updated by ECRI Institute on August 18, 2014.

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